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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,782	09/05/2001	Takashi Akita	213575US0PCT	4108
22850	7590	04/29/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/914,782

Applicant(s)

AKITA ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21 and 60-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 60-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

1. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states at page 115:

All of the publications, patents and patent applications cited herein are incorporated herein by reference in their entirety.

2. Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth In *Ex parte Raible*, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

\* \* \*

We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down

Art Unit: 1634

is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky, 474 F.2d 671, 177 USPQ 144 , (CCPA 1973).

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

3. At page 6 of the response received 01 April 2005 applicant's representative asserts that this objection is appropriate only "if only a portion of the document is to be incorporated.

Otherwise, Applicants may incorporate entire documents for that which they teach." (Emphasis in the original).

4. The above argument has been fully considered and has not been found persuasive. While the entire document may be useful, there needs to be an indication as to what usefulness the various parts of each document are to have. As applicant's representative has asserted, each document is to be incorporated by reference in its entirety. Page 3 of the specification teaches of WO98/51823. The front page of aid document is reproduced below.

Art Unit: 1634

PCT		WORLD INTELLECTUAL PROPERTY ORGANIZATION International Patent	
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)			
(31) International Patent Classification: C12Q 1/68	A1	(11) International Publication Number: WO 98/51823	(43) International Publication Date: 19 November 1998 (19.11.98)
(21) International Application Number: PCT/US98/09912	(22) International Filing Date: 15 May 1998 (15.05.98)	(74) Agents: BROOK, David, E. et al.; Hamilton, Bruce, Scott & Reynolds, P.C., Two Morris Drive, Lexington, MA 02173 (US).	
(30) Priority Data: 60046708 15 May 1997 (15.05.97) US 08/971,242 8 August 1997 (08.08.97) US	(32) Priority Date: 15 May 1997 (15.05.97) US 8 August 1997 (08.08.97) US	(33) Designated States: AL, CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(63) Related by Continuation (CON) or Continuation-In-Part (CIP) to Earlier Applications: US 08/971,242 (CIP) Filed on: 8 August 1997 (08.08.97) US 60046708 (CIP) Filed on: 15 May 1997 (15.05.97)		Published With international search report.	
(71) Applicant for all designated States except US: MOSAIC TECHNOLOGIES (US/US), 1106 Commonwealth Avenue, Boston, MA 02215 (US).			
(72) INVENTORS: ENE (73) INVENTOR/APPLICANTS (for US only): BOLES, Thomas C. (US/US), 1 Judith Lane, No. 6, Woburn, MA 02156 (US); MUEB, Andrew, R. (US/US), 481 Somerset Road, Cohasset, MA 02113 (US); KACON, Stephen, J. (US/US), 611 Park Oaks Avenue, Oak Park, IL 60302 (US); ABBANCA, Eric.			
(54) Title: ELECTROPHORETIC ANALYSIS OF MOLECULES USING IMMOBILIZED PROBES			
(57) Abstract: Methods of detecting target molecules using electrophoresis and media containing immobilized reagents are described.			

There is no indicating in the specification why the title page of this, or of any other patent publication is being relied upon, much less a showing of how the disclosures found on each page of each of the cited documents is to be applied to the instant invention. Accordingly, and in the absence of convincing evidence to the contrary, the objection to the specification is maintained.

Art Unit: 1634

5. The use of the trademark NYLON, TEFLON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 21 and 60-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re*

Art Unit: 1634

*Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

8. For convenience, claim 21 is reproduced below.

Claim 21 (Currently Amended): A method for determining the position of each fiber unit in the slice according to claim 16 each slice that comprises a fiber alignment, the method comprising the steps of:

- (a) cutting sequentially a fiber alignment obtained by binding and immobilizing fibers, to obtain a series of fiber alignment slices  $S(1)$ ,  $S(2)$ , ...,  $S(h)$ , ...,  $S(m)$ ;
- (b) selecting any given slice  $S(h)$  from  $m$  number of slices, and determining two-dimensional coordinates for each fiber unit contained in said slice  $S(h)$ , based on the coordinate reference ~~pointes~~ points in said slice  $S(h)$ ;
- (c) determining the two-dimensional coordinates of each fiber unit contained in slice  $S(i)$  located ~~steos~~ adjacent to said slice  $S(h)$ , based on the coordinate data of slice  $S(h)$  obtained in step (b) and the coordinate reference points in said slice  $S(i)$ ; and
- (d) repeating steps (b) and (c) to determine the two-dimensional coordinates of each fiber unit in said one or more successive and adjacent fiber alignment slice slices,  $S(j)$ ,  $S(k)$ , ...,  $S(m)$ , that comprise a fiber alignment, and wherein each slice comprises fiber units and reference points.

9. For purposes of examination, the "fiber" has been interpreted as encompassing any compound or polymer, organic or inorganic, that can exist in a form that would be construed as a

Art Unit: 1634

“fiber,” wherein said “fiber” may be comprised of an infinite number of filaments, and wherein the fiber and/or filaments may have virtually any secondary structure, be it ordered or random.

Such organic fibers have been construed as encompassing nucleic acids, polypeptides, long chain fatty acids, etc.

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10. Said claims have also been interpreted as encompassing “slices” of virtually any thickness, and that the “reference points” can be individual filaments, fibers, or some other feature that is recognizable. While the claimed method calls for the use of “reference points,” said reference points are not required to be fixed or bear any correlation to reference points found on any other slice, or that they even be the same reference points from one slide to another.

11. As presently worded, the number of fibers (and associated filaments, if any) that are associated with any “fiber alignment” can vary in number, type, and composition, not to mention taking on any secondary or higher order of structure. Additionally, the claims have been construed as not requiring any means of differentiating one fiber from that of another.

12. The specification does not set forth a reproducible procedure whereby one would be able to determine the position of each fiber unit in each slice of a fiber alignment.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 21 and 60-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



Art Unit: 1634

15. The term "adjacent" in claim 21 is a relative term, which renders the claim indefinite. The term "adjacent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

16. Via amendment received 01 April 2005, claim 21 was amended such that the term "close" was substituted with the term "adjacent." A review of the specification fails to locate a definition for "adjacent." Accordingly, Office has construed the term "adjacent" to mean close to, or nearby (*Webster's II New Riverside University Dictionary*, 1984, p. 78.). The aspect of something being close to or nearby renders claim 21 indefinite, as both are relative terms. Claims 60-73, which depend from claim 21, fail to overcome this issue and are similarly rejected.

17. In accordance with claim 63, the biological substance is "immobilized on the fiber, in the fiber, or both in and in the fibers." Claims 65-68, which depend from claim 63 seemingly require that a gel, not the fiber, comprise the immobilized biological substance. If the "immobilized biological substance" is in fact to be construed as part of the gel, then it is unclear as to how it is to be immobilized to the fiber. Accordingly, claims 63 and claims 65-68, which depend from said claim 63 are rejected under 35 USC 112, second paragraph.

### ***Conclusion***

18. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

Art Unit: 1634

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

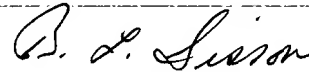
22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1634

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
26 April 2005

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